

## PATENT COOPERATION TREATY



## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference IT/DC/BR041161	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/FR2003/000078	International filing date ( <i>day/month/year</i> ) 10 janvier 2003 (10.01.2003)	Priority date ( <i>day/month/year</i> ) 10 janvier 2002 (10.01.2002)
International Patent Classification (IPC) or national classification and IPC C12Q 1/68		
Applicant BIO MERIEUX		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>

Date of submission of the demand 02 juin 2003 (02.06.2003)	Date of completion of this report 08 June 2004 (08.06.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FR2003/000078

**I. Basis of the report**

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

 the international application as originally filed. the description, pages 1-46, as originally filed,

pages \_\_\_\_\_, filed with the demand,

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

 the claims, Nos. 1-17, as originally filed,

Nos. \_\_\_\_\_, as amended under Article 19,

Nos. \_\_\_\_\_, filed with the demand,

Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

 the drawings, sheets/fig \_\_\_\_\_, as originally filed,

sheets/fig \_\_\_\_\_, filed with the demand,

sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

 the description, pages \_\_\_\_\_ the claims, Nos. \_\_\_\_\_ the drawings, sheets/fig \_\_\_\_\_

3.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

**Supplemental Box<sup>1</sup>**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.

The applicant is again reminded that inventions will not be examined unless they have been searched (PCT Rules 66.1(e) and 70.2(d)).

The International Searching Authority has determined that this international application contains more than one invention or group of inventions, namely:

**Invention 1:** claims 1 to 9 (all in part): Nucleotide sequence defined by SEQ ID NO 1, the complementary sequence thereof, sequences that hybridise specifically with said sequences, homologous sequences and any sequence including at least 5 contiguous nucleotides that are part of said sequences and at least 70 % identical thereto, probes and primers according to said sequences, reagents and biochips including at least one of said sequences, and uses thereof in methods for determining an original animal species in a sample that may contain an ingredient obtained from at least said species.

**Inventions 2 to 232:** claims 1 to 9 (all in part): The same definition as for invention 1, but applied to each of sequences SEQ ID NO 2 to 232.

**Invention 233:** claims 10 to 12 and 14 to 17 (all in part): Nucleotide sequence defined by SEQ ID NO 235, the complementary sequence thereof, sequences that hybridise specifically with said sequences, homologous sequences and any sequence including at least 5 contiguous nucleotides that are part of said sequences and at least 70 % identical thereto, reagents including at least one of said sequences, and uses thereof in methods for determining an original animal species in a sample that may contain an ingredient obtained from at least said

**Supplemental Box**  
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.

species.

**Invention 234:** claims 10 to 12 and 14 to 17 (all in part): Nucleotide sequence defined by SEQ ID NO 236, the complementary sequence thereof, sequences that hybridise specifically with said sequences, homologous sequences and any sequence including at least 5 contiguous nucleotides that are part of said sequences and at least 70 % identical thereto, reagents including at least one of said sequences, and uses thereof in methods for determining an original animal species in a sample that may contain an ingredient obtained from at least said species.

**Invention 235:** claims 10 to 12 and 14 to 17 (all in part): Nucleotide sequence defined by SEQ ID NO 237, the complementary sequence thereof, sequences that hybridise specifically with said sequences, homologous sequences and any sequence including at least 5 contiguous nucleotides that are part of said sequences and at least 70 % identical thereto, reagents including at least one of said sequences, and uses thereof in methods for determining an original animal species in a sample that may contain an ingredient obtained from at least said species.

**Invention 236:** claims 10 to 12 and 14 to 17 (all in part): Nucleotide sequence defined by SEQ ID NO 238, the complementary sequence thereof, sequences that hybridise specifically with said sequences, homologous sequences and any sequence including at least 5 contiguous nucleotides that are part of said sequences and at least 70 % identical thereto, reagents including at least one of said sequences, and uses thereof in methods for

**Supplemental Box**  
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.

determining an original animal species in a sample that may contain an ingredient obtained from at least said species.

**Invention 237:** claims 10 to 12 and 14 to 17 (all in part): Nucleotide sequence defined by SEQ ID NO 239, the complementary sequence thereof, sequences that hybridise specifically with said sequences, homologous sequences and any sequence including at least 5 contiguous nucleotides that are part of said sequences and at least 70 % identical thereto, reagents including at least one of said sequences, and uses thereof in methods for determining an original animal species in a sample that may contain an ingredient obtained from at least said species.

**Invention 238:** claims 10, 11 and 13 to 17 (all in part): Nucleotide sequence defined by SEQ ID NO 262, the complementary sequence thereof, sequences that hybridise specifically with said sequences, homologous sequences and any sequence including at least 5 contiguous nucleotides that are part of said sequences and at least 70 % identical thereto, reagents including at least one of said sequences, and uses thereof in methods for determining an original animal species in a sample that may contain an ingredient obtained from at least said species.

**Inventions 239 to 247:** claims 10, 11 and 13 to 17 (all in part): The same definition as for invention 238, but applied to each of sequences SEQ ID NO 263 to 271.

**Inventions 248 to 257:** claims 1 to 9 (all in part): The same definition as for invention 1, but applied to each of sequences SEQ ID NO 242 to 261.

**Supplemental Box**  
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.

The common technical feature in the present application is the use of nucleotide sequences for determining an original animal species in a sample. The use of nucleotide sequences for determining an original animal species in a sample is already known from the prior art (see Matsunaga et al., 1999 (D1), Matsunaga et al., 1999 (D2), Colgan et al., 2001 (D3), and Matsunaga et al., 1998 (D4)).

In the light of the prior art (documents D1 to D4), the problem that the present application is intended to solve is that of identifying alternative nucleotide sequences for determining an animal species. The solutions are the various nucleotide sequences SEQ ID NO 1 to 232, 235 to 239 and 242 to 271.

Considering the prior art and the differences between the solutions according to the present application, as well as the fact that no other technical features can be considered to be common technical features in the light of the prior art, the Search Division considers that the inventions claimed are not linked by a common inventive concept and thus lack unity of invention.

Since none of the additional fees the applicant was requested to pay have been paid, the present written opinion has been established on the basis of invention 1 only, that is claims 1 to 9 (all in part).

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1, 2, 4	YES
	Claims	3, 5-9	NO
Inventive step (IS)	Claims		YES
	Claims	1, 2, 4	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

## 2. Citations and explanations

## 1. RELEVANT DOCUMENTS

Reference is made to the following documents (D) in the present opinion. The numbering given below will be used throughout the rest of the procedure.

D1: MATSUNAGA T ET AL: 'A quick and simple method for the identification of meat species and meat products by PCR assay.' MEAT SCIENCE, vol. 51, no. 2, February 1999 (1999-02), pages 143-148, XP002225826 ISSN: 0309-1740 cited in the application

D2: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1999, MATSUNAGA TAKAMITSU ET AL: 'Effects of processing conditions on species identification of meat products.' XP002225829 Database accession no. PREV199900277255 & NIPPON SHOKUHIN KAGAKU KOGAKU KAISHI, vol. 46, no. 3, 1999, pages 187-194, ISSN: 1341-027X

D3: COLGAN S ET AL: 'Development of a DNA-based assay for species identification in meat and bone meal.' FOOD RESEARCH INTERNATIONAL, vol. 34, no. 5, 2001, pages 409-414, XP002225827

ISSN: 0963-9969

D4: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1998, MATSUNAGA TAKAMITSU ET AL: 'Identification of meat species based on the difference of 18 S ribosomal RNA genes.' XP002225830 Database accession no. PREV199900149131 & NIPPON SHOKUHIN KAGAKU KOGAKU KAISHI, vol. 45, no. 12, 1998, pages 719-723, ISSN: 1341-027X

D5: US-A-4 912 038 (CORDELL BARBARA ET AL) 27 March 1990 (1990-03-27)

D6: MEYER ROLF ET AL: 'PCR-based DNA analysis for the identification and characterization of food components.' LEBENSMITTEL-WISSENSCHAFT & TECHNOLOGIE, vol. 29, no. 1-2, 1996, pages 1-9, XP002225828 ISSN: 0023-6438

D7: DE 198 39 573 A (KRECH RALPH; ROELLEKE SABINE (AT)) 9 March 2000 (2000-03-09)

## 2. NOVELTY (PCT Article 33(2))

- 2.1 D1 (cf. page 145, figures 2-6) describes the determination of an original animal species in a sample using a multiplex PCR.
- 2.2 D2 describes the same thing.
- 2.3 D3 and D4 (cf. page 145, figures 2-6) describe the determination of an original animal species in a sample using a PCR.
- 2.4 D5 describes probe 1199 (cf. column 20, line 22) which is 82 % identical to SEQ ID NO 1. Therefore, claims 3 and 4 to 9 are not novel.

2.5 The present application fails to comply with the requirements of PCT Article 33(2) since the subject matter of claims 3 and 4 to 9 is not novel over the prior art as defined in the Regulations (PCT Rule 64.1-64.3).

3. INVENTIVE STEP (PCT Article 33(3))

3.1 Document D1, which is considered to be the closest prior art (cf. 2.1), differs from claims 1 and 4 in that sequence SEQ ID NO 1 is used.

3.2 The problem that the present invention is intended to solve can thus be considered to be that of identifying alternative sequences for determining an original animal species in a sample.

3.4 The solution proposed in claims 1 and 4 of the present application is sequence SEQ ID NO 1. This solution cannot be considered to involve an inventive step (PCT Article 33(3)), for the following reason:

3.4.1 Other sequences specific to a class of animals have already been used for the same purpose in D1. Therefore, it is obvious for a person skilled in the art to implement these features when seeking to identify alternative sequences for determining an original animal species in a sample.

3.5 Dependent claim 2 does not contain any features which, when combined with the features of any one of the claims to which it refers, might define subject matter that complies with the requirements of novelty and/or inventive step of the PCT.

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3.6 It follows that claims 1 and 4 fail to comply with the requirements of PCT Article 33(3) since the subject matter of claims 1 and 4 is not inventive in the light of the prior art.